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REMARKS

Status of the claims

Claims 1-16 and 18-26 are pending in this application. Claims 7-10, 15 and 16 have been withdrawn from consideration pursuant to a requirement for restriction, and claim 17 has been canceled without prejudice or disclaimer. Claims 6 and 22 are objected to as being dependent upon a rejected base claim. Claims 1-5, 11-14 and 17-21 have been rejected.

Support for the amendment to claim 1 and new claims 23, 24 and 26 can be found, for example, in original claims 1 and 17 and in paragraphs [0011], [0029] and [0031] of the specification. Support for new claim 25 can be found, for example, in paragraph [0045] of the specification.

Objected to claims 6 and 22 have been amended to incorporate limitations of the claim(s) from which they depend.

No new matter is added.

Rejection under 35 U.S.C. 102(b)--Hariharan et al.

Claims 1-5, 11, 13, 14, 18 and 20 have been rejected under 35 U.S.C. 102(b) as being anticipated by Hariharan et al. US 5,916,968 (Hariharan). This rejection and its accompanying remarks are respectfully traversed.

The rejected claims are drawn to implantable or insertable medical devices comprising a therapeutic agent and a polymeric release region comprising a graft copolymer wherein one of the main chain and graft chains has a low Tg (rubbery phase) and the other has a high Tg (hard phase).

The graft copolymers disclosed by Hariharan have a main chain of acrylic/vinyl monomer copolymer of low Tg with a graft polymer chain of undisclosed Tg. The copolymer of Hariharan is used as an adhesive for transdermal patches and wound dressings. The essential concept of Hariharan is that the adhesive comprising the graft copolymer is resistant to plasticization by skin penetration enhancers contained in a drug formulation in the transdermal patches/wound dressings for which the adhesives are used.

Several distinctions between the present claims and Hariharan are immediately apparent, which distinctions rule out anticipation.

To whatever extent the examiner considers that the reference accidentally discloses the here-claimed invention, i.e., that the present invention might be inherent in Hariharan, no case for inherency has been made out. A holding of inherency must flow as a necessary conclusion from the prior art, not simply a possible one. See MPEP 2163.07(a). See also *In re Rijckaert*, 28 U.S.P.Q.2d 1955, 1957 (Fed. Cir. 1993), *In re Oelrich*, 666 F.2d 578, 581,212 U.S.P.Q. 223 (Fed. Cir. 1981), *Ex parte Levy*, 17 U.S.P.Q.2d 1461,1464 (BPAI 1990). In other words, the fact that some of the listed grafted chains may be hard is not adequate For anticipation a reference "must sufficiently describe the claimed invention to have placed the public in possession of it." *Paperless Accounting, Inc. v. Bay Area Rapid Transit System*, 804 F.2d 659, 231 U.S.P.Q. 649, 653 (Fed. Cir. 1986).

A second critical distinction is that Hariharan is drawn to adhesives for wound dressings and transdermal patches, whereas the instant claims are drawn to implantable or insertable medical devices. The examiner has taken the erroneous position that the recitation "implantable" or "insertable" is the recitation of an intended use. In this case, it will be apparent to anyone skilled in this art that the controverted limitation relates to a structural feature. *In re Paulsen*, 30 F.3d 1475, 31 U.S.P.Q.2d 1671, 1673 (Fed. Cir. 1994), *In re Swinehart*, 439 F.2d 210, 169 U.S.P.Q. 226, 228 (CCPA 1971), *In re Walles*, 366 F.2d 786, 151 USPQ 185, 190 (CCPA 1966), *Ex parte Schundehutte*, 184 USPQ 697 (BPAI 1974). On the issue of functional limitations generally, see *In re Fuetterer*, 319 F.2d 259, 138 U.S.P.Q. 217. 222 (CCPA 1963).

As to those claims that recite "adapted to," that recitation also connotes a property, not an intended use. "Adapted to" language is conventional apparatus or article language. It is not simply an intended use, but is well established as being a structural limitation. *In re Paulsen*, 30 F.3d 1475, 31 U.S.P.Q.2d 1671, 1673 (Fed. Cir. 1994), *In re Walles*, 366 F.2d 786, 151 U.S.P.Q 185, 190 (CCPA 1966), *Ex parte Schundehutte, supra.*

No one skilled in this art would consider implanting or inserting a transdermal patch or wound dressing of the type disclosed by Hariharan into a body as opposed to placing it onto a body.

Finally, claim 1 and new claim 26 are presently directed to specifically identified implantable or insertable medical devices whose structural requirements (e.g., shape, dimension, etc.) could not possibly be provided by an adhesive patch/dressing like that described in Hariharan, even if it were implanted or inserted into the body.

For the foregoing reasons, it is respectfully requested that this rejection be reconsidered and withdrawn.

Rejection under 35 U.S.C. 102 (b)--Kronfli et al.

Claims 1, 2, 11-14 and 17-21 have been rejected under 35 U.S.C. 102(b) as being anticipated by Kronfli et al. GB 2271717 (Kronfli). This rejection and its accompanying remarks are respectfully traversed.

As noted above, the rejected claims are drawn to implantable or insertable medical devices comprising a therapeutic agent and a polymeric release region comprising a graft copolymer wherein either one of the main chain and graft chains has a low Tg (rubbery phase) and the other has a high Tg (hard phase).

The graft copolymers disclosed by Kronfli have a hydrophobic main chain and hydrophilic side chains. See the Abstract and throughout the specification. Kronfli discloses only transdermal patches in any detail, particularly nicotine patches. In general, this reference suffers from the same defects as Hariharan.

As stated above, no one skilled in the medical arts would consider implanting a transdermal patch into a patient's body. The incidental disclosure of "catheters," ocular inserts, vaginal rings, and subcutaneous implants (e.g., for contraception) does not rise to the level of an anticipation where it is lost within the entire disclosure, the subject of which is transdermal patches. See *Paperless Accounting, supra.*

The issue of intended use versus structural limitations has also been discussed above with *In re Paulsen*, *In re Walles*, and *Ex parte Schundehutte* cited as authority.

Finally, claim 1 is presently directed to implantable or insertable medical devices whose structural requirements (e.g., shape, dimension, etc.) could not possibly be provided by an adhesive patch, catheter, contraceptive implant, or other device described in Kronfli.

For at least the foregoing reasons, it is respectfully requested that this rejection be reconsidered and withdrawn.

Rejection under 35 U.S.C. 103(a)--Hariharan

Claims 1-5, 11, 13, 14, 18 and 20 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Hariharan. This rejection and its accompanying remarks are respectfully

traversed.

The examiner has stated that this rejection is based on the reference disclosure of the following: "Specific grafted polymers will depend on the specific enhancers used in a particular drug delivery or wound dressing inasmuch as different enhancers will present different solubility consideration for the adhesives."

It is not clear, and the examiner has not explained, how that broad statement would teach one how to vary the polymer hardness according to the enhancer used even in Hariharan. Since the devices here claimed are not adhesive-bearing patches and there are no skin penetration enhancers to be considered, the quoted statement is not at all relevant to the instant claims.

For the foregoing reasons, it is respectfully requested that this rejection be reconsidered and withdrawn.

Allowable Subject Matter

Claims 6 and 22 were objected to as being dependent upon a reject base claim. These claims have now been rewritten in independent form.

Conclusion

In light of the foregoing remarks, applicants believe that all rejections of record have been obviated, and allowance of this application is respectfully requested. If the Examiner believes there are still unresolved issues, a telephone call to the undersigned at (703) 433-0510 would be welcomed.

The Office is authorized to charge any additional fees required to deposit account number 50-1047.

Respectfully submitted,

David B. Bonham
Registration No. 34,297

Mayer & Williams PC
251 North Ave. West, 2nd Floor
Westfield, NJ 07090
Tel.: 703-433-0510
Fax: 703-433-2362